

Remarks:

Claims 1-16 are pending and claim 9 has been withdrawn.

Claims 1-8 have been rejected as anticipated under 35 U.S.C. § 102(e) by Zhang et al. (US 2004/0265388) (hereinafter, "the '388 Publication").

Claim 10 has been rejected as unpatentable under 35 U.S.C. §103(a) over the '388 Publication.

Claims 1-8 and 10-16 have been rejected as unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 6,147,122 to Mirejovsky et al. ("Mirejovsky") in view of U.S. Patent No. 7,097,849 to Mishra et al. ("Mishra") as evidenced by *Developmental and Comparative Immunology*, 1999, vol. 23, pp. 329-344 by Bulet et al. ("Bulet").

Claim 1 has been provisionally rejected based on obviousness-type double patenting over claims 1, 2 and 6 of co-pending Application No. 10/629,308 to Zhang et al. ("the '308 Application") as evidenced by Bulet. Claim 1 is also provisionally rejected based on obviousness-type double patenting over claims 18 and 23 of co-pending Application No. 10/10/677,747 to Zhang et al. ("the '747 Application") as evidenced by Bulet. Claim 1 is further provisionally rejected based on obviousness-type double patenting over claims 1, 35 and 36 of co-pending Application No. 10/10/766,631 to Zhang et al. ("the '631 Application") as evidenced by Bulet.

Claims 1-8: 35 U.S.C. § 102(e), The '388 Publication

Applicants traverse the Office Action's anticipation rejection of claims 1-8 based on the '388 Publication because Applicants are entitled to an earlier priority date. The pending application is entitled to the benefit of U.S. Provisional Patent Application No. 60/422,196 filed on October 29, 2002 under 35 U.S.C. § 119(e)(1). The pharmaceutical composition comprising propofol and cysteine of claim 1 was disclosed in Application No. 60/422,196.

As its earliest possible critical date under 35 U.S.C. § 102(e), the '388 Publication, can refer back to December 30, 2002 based on the filing date of U.S. Provisional Application No. 60/436,979 to which the '388 Publication claims priority. See MPEP 706.02(f)(1).

Inasmuch as the pending application's priority date of October 29, 2002 precedes the '388 Publication's earliest critical date of December 30, 2002 the '388 Publication is not prior art

under § 102(e). Applicants respectfully submit that the rejection should therefore be withdrawn.

Claim 10: 5 U.S.C. § 103(a), The '388 Publication

Based upon the Applicants' entitlement to an October 29, 2002 priority date, as explained above, the Office Action's rejection of claim 10 as obvious should also be withdrawn because the '388 Publication is not prior art under § 102(e).

Claims 1-8 and 10-16: 35 U.S.C. § 103(a), Mirejovsky and Mishra and Bulet

Applicants traverse the Office Action's rejection of claims 1-8 and 10-16 under § 103(a) based on Mirejovsky in view of Mishra further in view of Bulet.

As a preliminary matter, Applicants maintain their position as stated in their previous Amendment of July 11, 2007 that the Bulet reference does not teach cysteine as an antimicrobial agent. Bulet is a study of selected immunological mechanisms of insects. Bulet, abstract. Bulet does not teach that cysteine itself has antimicrobial activity nor does it suggest that cysteine would have antimicrobial properties in other environments. The insect defensins described by Bulet are "36 to 46 amino acids long with the exception of 51-residue bee and bumblebee defensins... ." Bulet, p. 330. Bulet teaches a few proteins that have antimicrobial properties include cysteine among their linked amino acid constituents. In no way does Bulet teach that cysteine, by itself, has antimicrobial properties. Applicants respectfully traverse the Office Action's *post hoc* assumption in this regard. Inasmuch as the Office Action relies exclusively upon Bulet for a teaching of the cysteine limitation of claim 1 and neither Mirejovsky nor Mishra teach, singly or in combination, cysteine, Applicants respectfully submit that the rejection is improper and should be withdrawn.

Assuming, for the sake of argument that cysteine as an antimicrobial component can be inferred from Bulet, based on the cited references one skilled in the art would have had no reasonable expectation of success in formulating a pharmaceutical composition comprising propofol and cysteine as claimed in claim 1 and claim 11. That is, none of the references taken singly or in combination would lead one of ordinary skill in the art to select cysteine from among the myriad of known antimicrobial agents to formulate the pharmaceutical composition as claimed. Nor does the known prior art provide any basis to predict that cysteine, as an isolated chemical entity, unlike its disclosed environment but as part of an insect defense

mechanism, would function as an effective preservative in a pharmaceutical composition much less in Applicants' specific anesthetic composition.

Mirejovsky teaches propofol compositions including a preservative but only teaches sulfite salts as that preservative. Mirejovsky abstract. Mishra teaches that its propofol compositions "may optionally contain other pharmaceutically acceptable agents, for example, other antimicrobial agents...." Mishra, col. 5, lines 47-51. Both references, however, are silent with respect to cysteine or components structurally similar to cysteine. Neither reference teaches a mode of action that is similar to that of insect defensins as described in the Bulet reference. Bulet p. 332. For its part, Bulet does not teach the use of cysteine as a preservative in *any* pharmaceutical composition much less a propofol pharmaceutical composition.

Even if one were to assume that these references would suggest or make obvious trying some combination of the constituents in these references, the possible combinations are so numerous as to be effectively infinite. This rationale therefore can not support a proper obvious rejection.

Moreover, there is nothing to suggest a reasonable expectation of success with any such combination. Accordingly, Applicants respectfully submit that the rejection is improper and should be withdrawn.

Claim 1: Obviousness-type Double Patenting, Zhang et al. applications + Bulet

Applicants will address these rejections, if needed, when the claims of this application have been deemed otherwise allowable, or one or more of the co-pending applications have issued or been allowed, and this rejection has been made final. By way of transversal, however, Applicants note that the rejection is improper and cannot be supported, in any event, because of the shortcomings of the secondary reference, Bulet, as noted above, to suggest that cysteine in and of itself may act as an antimicrobial agent in a propofol composition.

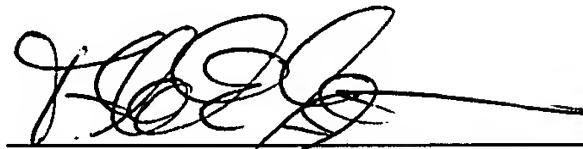
Appln. No.: 10/695,291
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Reply to Office Action of October 9, 2007

J&J-102US

Conclusion

For the foregoing reasons, Applicants believe the application to be in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,



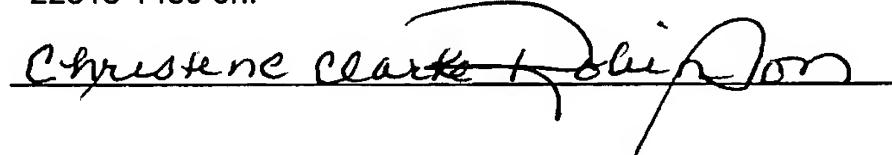
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